IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	J. Christopher Flaherty	Examiner: MacNeill, E.
Serial No.:	10/662,761	Group Art Unit: 3763
Filed:	September 15, 2003	Docket No.: INSL-0125DV
Title:	Plunger Assembly for Patient Infusion Device	

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Applicant has reviewed the Office Action mailed on September 18, 2006.

This response is accompanied by a Petition, as well as the appropriate fee, to obtain a 3-month extension of the period for responding to the Office action.

Amendments to the claims begin on page 2 of this paper.

Remarks begin on page 9 of this paper.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-30 (canceled).

31 (original). A device for delivering fluid to a patient, comprising:

an exit port assembly;

a dispenser including,

a container having an outlet connected to the exit port assembly, an inlet for connection to a reservoir, and a side wall extending along a longitudinal axis towards the outlet and the inlet, and

a plunger assembly received in the container and including,

a first lateral segment extending laterally with respect to the longitudinal axis of the container and contacting the side wall of the container,

a second lateral segment positioned between the first lateral segment and the outlet of the container, the second lateral segment extending laterally with respect to the longitudinal axis of the container and contacting the side wall of the container, and longitudinally spaced from the first lateral segment, and

a shape memory element having a changeable length decreasing from an uncharged length to a charged length when at least one charge is applied to the shape memory element, the shape memory element connecting the first and the second lateral segments.

32 (original). A device according to claim 31, wherein the shape memory element is made of a nickel and titanium alloy.

33 (original). A device according to claim 31, wherein the shape memory element is elongated and extends between a first end connected to the first lateral segment and a second end connected to the second lateral segment.

34 (original). A device according to claim 33, wherein the shape memory element comprises a wire having a generally circular cross-section.

35 (original). A device according to claim 33, wherein the shape memory element comprises a coiled spring.

36 (original). A device according to claim 33, wherein the shape memory element comprises a collapsible bellows.

37 (original). A device according to claim 31, wherein the plunger assembly further includes a rigid projection positioned between the first and the second lateral segments and extending parallel with the longitudinal axis of the container for limiting the closeness of the first and the second lateral segments.

38 (original). A device according to claim 37, wherein the rigid projection of the plunger assembly has a substantially predetermined length extending parallel with the longitudinal axis of the container.

39 (original). A device according to claim 38, wherein the shape memory element has a substantially predetermined uncharged length.

40 (original). A device according to claim 31, wherein the shape memory element has a substantially predetermined uncharged length and a substantially predetermine charged length.

41 (original). A device according to claim 31, wherein the plunger assembly is prevented from rotating with respect to the side wall of the container.

42 (original). A device according to claim 31, wherein the first lateral segment is fixed in position with respect to the side wall of the container.

43 (original). A device according to claim 31, wherein the plunger assembly further includes a cooler assembly in contact with the shape memory element.

44 (original). A device according to claim 43, wherein the cooler assembly includes a thermoelectric cooler.

45 (original). A device according to claim 43, wherein the cooler assembly includes a heat sink.

46 (original). A device according to claim 31, wherein the container includes a check valve assembly within the outlet.

47 (original). A device according to claim 31, wherein the container includes a check valve assembly within the inlet.

48 (currently amended). A device according to claim 31, wherein:

the side wall of the container includes a first section extending from the outlet and the inlet of the container parallel with the longitudinal axis and a second section extending from the first section parallel with the longitudinal axis, and wherein the first section of the side wall has an internal cross-sectional dimension that is unequal to an internal cross-sectional dimension of the second section of the side wall; and

the first and the second lateral segments of the plunger assembly are received in the second section of the side wall of the container, and the plunger assembly further includes a strut extending from the second lateral segment and slidingly received in the first section of the side wall of the container, wherein the strut is sized and shaped to provided a substantially fluid-tight seal between the first section of the side wall and the strut.

49 (original). A device according to claim 31, further comprising a reservoir connected to the inlet of the dispenser.

50 (original). A device according to claim 49, wherein the reservoir contains a therapeutic fluid.

51 (original). A device according to claim 50, wherein the therapeutic fluid is insulin.

52 (original). A device according to claim 31, wherein the exit port assembly includes a transcutaneous patient access tool.

53 (original). A device according to claim 52, wherein the transcutaneous patient access tool comprises a needle.

54 (original). A device according to claim 31, further comprising a local processor connected to ends of the shape memory element through conductive wires and programmed to provide charges to the shape memory element based upon flow instructions.

55 (original). A device according to claim 54, further comprising a power supply connected to the local processor.

56 (original). A device according to claim 31, further comprising:

a local processor electrically connected to the shape memory element of the plunger assembly and programmed to provide electrical charges to the shape memory element based upon flow instructions;

a wireless receiver connected to the local processor for receiving flow instructions from a separate, remote control device and delivering the flow instructions to the local processor; and

a housing containing the dispenser, the exit port assembly, the local processor and the wireless receiver, and wherein the housing is free of user input components for providing flow instructions to the local processor.

57 (original). A system including a fluid delivery device according to claim 56, and further comprising a remote control device separate from the fluid delivery device and including:

a remote processor;

user interface components connected to the remote processor for allowing a user to provide flow instructions to the remote processor; and

a transmitter connected to the remote processor for transmitting the flow instructions to the receiver of the fluid delivery device.

58 (original). A device according to claim 31, wherein the shape memory element comprises two-way shape memory material and the shape memory element biases the first and the second lateral segments together when at least one charge is applied to the shape memory element and biases the first and the second lateral segments apart when at least one charge is removed.

59 (original). A device according to claim 31, wherein the shape memory element comprises one-way shape memory material and biases the first and the second lateral segments together when at least one charge is applied to the shape memory element.

60 (original). A device according to claim 59, wherein the plunger assembly further includes a spring biasing the first and the second lateral segments.

61 (original). A device for delivering fluid to a patient, comprising:

an exit port assembly;

a dispenser including,

a container having an outlet connected to the exit port assembly, an inlet for connection to a reservoir, and a side wall extending along a longitudinal axis towards the outlet and the inlet, and

a plunger assembly received in the container and including,

a first lateral segment extending laterally with respect to the longitudinal axis of the container and contacting the side wall of the container,

a second lateral segment positioned between the first lateral segment and the outlet of the container, the second lateral segment extending laterally with

respect to the longitudinal axis of the container and contacting the side wall of the container, and longitudinally spaced from the first lateral segment,

a spring biasing the first and the second lateral segments longitudinally apart, and

an actuator arranged to overcome the spring and bias the first and the second lateral segments longitudinally together upon actuation.

62 (original). A device according to claim 61, wherein the plunger assembly further includes a rigid projection positioned between the first and the second lateral segments and extending parallel with the longitudinal axis of the container for limiting the closeness of the first and the second lateral segments.

63 (original). A device according to claim 62, wherein the rigid projection of the plunger assembly has a substantially predetermined length extending parallel with the longitudinal axis of the container.

64 (original). A device according to claim 61, wherein the plunger assembly is prevented from rotating with respect to the side wall of the container.

65 (original). A device according to claim 61, wherein the first lateral segment is fixed in position with respect to the side wall of the container.

66 (original). A device according to claim 61, wherein the container includes a check valve assembly within the outlet.

67 (original). A device according to claim 61, wherein the container includes a check valve assembly within the inlet.

68 (original). A device according to claim 61, wherein:

the side wall of the container includes a first section extending from the outlet and the inlet of the container parallel with the longitudinal axis and a second section extending from the first section parallel with the longitudinal axis, and wherein the first section of the side wall has an internal cross-sectional dimension that is unequal to an internal cross-sectional dimension of the second section of the side wall; and

the first and the second lateral segments of the plunger assembly are received in the second section of the side wall of the container, and the plunger assembly further includes strut extending from the second lateral segment and slidingly received in the first section of the

side wall of the container, wherein the strut is sized and shaped to provided a substantially fluid-tight seal between the first section of the side wall and the strut.

69 (original). A device according to claim 61, further comprising a reservoir connected to the inlet of the dispenser.

70 (original). A device according to claim 69, wherein the reservoir contains a therapeutic fluid.

71 (original). A device according to claim 70, wherein the therapeutic fluid is insulin.

72 (original). A device according to claim 61, wherein the exit port assembly includes a transcutaneous patient access tool.

73 (original). A device according to claim 72, wherein the transcutaneous patient access tool comprises a needle.

74 (original). A device according to claim 61, further comprising a local processor connected to the actuator of the plunger assembly and programmed to actuate the actuator based upon flow instructions.

75 (original). A device according to claim 74, further comprising a power supply connected to the local processor.

76 (original). A device according to claim 61, further comprising:

a local processor electrically connected to the actuator of the plunger assembly and programmed to actuate the actuator based upon flow instructions;

a wireless receiver connected to the local processor for receiving flow instructions from a separate, remote control device and delivering the flow instructions to the local processor; and

a housing containing the dispenser, the exit port assembly, the local processor and the wireless receiver, and wherein the housing is free of user input components for providing flow instructions to the local processor.

77 (original). A system including a fluid delivery device according to claim 76, and further comprising a remote control device separate from the fluid delivery device and including:

a remote processor;

user interface components connected to the remote processor for allowing a user to provide flow instructions to the remote processor; and

a transmitter connected to the remote processor for transmitting the flow instructions to the receiver of the fluid delivery device.

78 (original). A device according to claim 61, wherein the actuator of the plunger assembly comprises a piezoelectric element.

79 (original). A device according to claim 61, wherein the actuator of the plunger assembly comprises a solenoid assembly.

80 (canceled).

81 (canceled).

82 (original). A device according to claim 48, wherein the internal cross-sectional dimension of the first section of the side wall of the container is smaller than the internal cross-sectional dimension of the second section of the side wall.

83 (original). A device according to claim 68, wherein the internal cross-sectional dimension of the first section of the side wall of the container is smaller than the internal cross-sectional dimension of the second section of the side wall.

REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on September 18, 2006, and the references cited therewith.

Claim Objections

In paragraph 1 of the office action, the examiner objected to claim 48 because of a missing article before the word "strut." Applicant has amended claim 48 to insert the missing article "a."

Double Patenting Rejection

In paragraph 3 of the office action, the examiner rejected claims 31-79, 82 and 83 under the judicially created doctrine of double patenting over claims 1-22 U.S. Patent No. 6723072 and claims 1-135 of U.S. Patent No. 6656158.

Applicant submits that this grounds of rejection is improper with respect to both cited patents.

The present application is a divisional of USP 6723072. The pending claims were canceled from the '072 patent in response to a restriction requirement. Accordingly, the '072 patent may not be asserted as a basis for a double patenting rejection.

Concerning the '158 patent, applicant submits that nothing in the disclosure or claims of the '158 patent teaches or suggests the present invention. In particular, and without limitation, the '158 patent does not teach or suggest a fluid delivery device having a plunger having first and second lateral segments and, as set forth in claim 31, a shape memory element connecting the first and second segments, or, as set forth in claim 61, a spring biasing the segments apart and an actuator arranged to overcome the spring. An exemplary embodiment of such an "inch-worm" type drive for a "syringe pump" is shown in Figures 2 and 2A-2C of the present invention. While the '158 patent, does teach various drive mechanisms for fluid delivery devices, including the use of a shape memory element in such drives, it does not teach or suggest a device having a plunger as set forth in claims 31 and 61.

In view of the foregoing, applicant submits that the obviousness type double patenting rejections of claims 31 and 61 and all of the dependent claims thereform are improper and should be withdrawn.

'102 Rejection of the Claims

In paragraph 5 of the office action, the examiner rejected claims 31-33, 36-42, 49-59, 61-65 and 69-79 under 35 USC 102(e) as being anticipated by USP 7070577 ("Haller").

As noted above, the present invention, as set forth in claim 31 requires a plunger assembly having first and second lateral segments, each in contact with the sidewall of the container. The lateral segments are connected by a shape memory element. Similarly, claim 61 requires first and second lateral segments biased apart by a spring and having an actuator to overcome the spring. As such, the fluid delivery device of the present invention, as set forth in claims 31 and 61, dispenses fluid by the movement of the plunger assembly through the container or reservoir. The lateral segments and shape memory element enable the movement of the plunger through the container causing displacement of the fluid from the container. In this regard, the present invention is directed to a "syringe" type pump with a self-advancing plunger.

By contrast, Haller teaches a pump with no plunger or plunger assembly at all. Instead, Haller teaches a pump with a collapsible reservoir as opposed to a syringe pump. The elements 42, 53 and 54, which the examiner identified as part of a plunger assembly are, in fact, part of a valve assembly (see, e.g. Haller at col. 6, lines 17-67). Thus, the Haller pump functions not by the movement of a plunger through a static reservoir, but rather by the collapse of the reservoir regulated by the opening and closing of a valve. Thus Haller does not teach the specific elements of either claims 31 or 61. Nor does Haller, whether considered alone or together with any other reference of record teach or suggest the fluid delivery device as set forth in claims 31 and 61.

Accordingly, applicant submits that the rejections of claims 31 and 61 under 35 USC 102(e) as being anticipated by Haller are improper and should be withdrawn. Moreover, since claims 32-59 and 62-79, and 82-83 depend variously from claims 31 and 61, those rejections are likewise improper and should be withdrawn.

In paragraph 6 of the office action, the examiner rejected claims 31, 61, 34, 35, 60, 43-45, 46, 66, 47, 67, 48, 68, 82 and 83 under 35 USC 102(e) as being anticipated by USP 7052251 ("Nason"). Nason, however, like Haller, teaches valve driven pump, not a syringe pump. While Nason, unlike Haller, can be said to have a plunger assembly (piston 120) that moves

(reciprocates) in a container (pumping chamber 104), the plunger assembly does not comprise first and second lateral segments coupled by a either a shape memory element or a spring/actuator. The plunger portion (piston 120) of Nason is a unitary body whose lateral segments, to the extent such elements can be said to exist at all, are formed from the same unitary body and are not connected to one another by a shape memory element or spring/actuator. Nason does teach the use of a shape memory element, and/or spring/actuator, to move the piston 120, but the SME acts to move the piston relative to the chamber. It does not couple any lateral segments of the piston or, thereby, move the lateral segments of the piston relative to one another. Accordingly, Nason does not literally teache all of the elements of claim 31 or claim 61. Nor does Nason suggest such elements since the functioning of the Nason pump is completely different from that of the fluid delivery device claimed in claims 31 and 61.

Accordingly, applicant submits that the rejections of claims 31 and 61 under 35 USC 102(e) as being anticipated by Nason are improper and should be withdrawn. Moreover, since claims 34, 35, 60, 43-45, 46, 66, 47, 67, 48, 68, 82 and 83 depend variously from claims 31 and 61, those rejections are likewise improper and should be withdrawn.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (781-457-4717) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 503188.

Respectfully submitted,

Date March 19, 2007

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